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10/551,350	10/19/2006	Devin Leake	16542.16.1a.3	3238

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EXAMINER	
BOWMAN, AMY HUDSON	

ART UNIT	PAPER NUMBER
1635	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,350	LEAKE ET AL.	
	Examiner	Art Unit	
	AMY BOWMAN	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *201-203,205-209,211,213,214,220,221,224-228 and 230-233* is/are pending in the application.

4a) Of the above claim(s) *203, 205, 208, 209, 211, and 214* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *201, 202,206, 207,213,220,221,224-228 and 230-233* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 September 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/24/09*.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application

6)☐ Other: _____.

DETAILED ACTION

Status of Application/Amendment/Claims

Applicant's response filed 1/8/09 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 9/8/08 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 201-203,205-209,211,213,214,220,221,224-228 and 230-233 are pending in the application.

In applicant's response filed on 7/10/08, applicant elected the following species having the following modification schematic without traverse: a first nucleotide of the sense strand closest to the 5' end of the sense strand having a 2'-O-alkyl modification; a second nucleotide of the sense strand next closest to the 5' end of the sense strand having a 2'-O-alkyl modification; a first nucleotide of the antisense strand closest to the 5' end of the antisense strand is phosphorylated at its 5' end and the sense strand is devoid of a phosphate at its 5' end; the antisense region includes at least one nucleotide other than first and second antisense nucleotides having a 2' modification; the antisense strand has at least one phosphorothioate internucleotide linkage; a 3' overhang of 1-5

nucleotides on at least one of the sense or antisense strand; and at least one conjugate cholesterol coupled to the 3' end of the sense strand.

This application contains claims 203, 205, 208, 209, 211 and 214, as well as subject matter of claims that is not directed to the elected invention, which is drawn to an invention nonelected **without traverse** in the reply filed on 7/10/08. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant's amendments and/or arguments filed on 1/8/09, with respect to the rejections under 35 USC 102 and 35 U.S.C. 103, have been fully considered and are persuasive. Therefore, these rejections have been withdrawn.

However, due to the instant claim amendments, a modified rejection under 35 USC 112, 1st paragraph and new grounds of rejection is applied as set forth below.

It is noted that applicant's claim for priority is consistent with the priority chain on the Bib data sheet.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 2/24/09 has been considered by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 201, 202, 206, 207, 213, 220, 221, 224-228, and 230-233 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

Instant claim 201 has been amended to require for the "rest of the sense nucleotides other than the first and second nucleotides each include a 2'-OH". Upon a review of the instant specification, and particularly at the locations pointed to by applicant, support is not evident for an embodiment with each of the specific structural elements in combination as instantly claimed. Instant claim 201 requires for the first and second nucleotides closest to the 5' end of the sense strand to have a 2'-O-alkyl modification and the rest of the nucleotides to include a 2'-OH. Claim 202 requires 5'-phosphorylation on the 5' end of the antisense strand, wherein the sense strand is devoid of a phosphate at the 5'end.

However, support is not evident for this specific schematic. In the originally filed claims, the only modification schematic that required for all of the rest of the nucleotides other than the first two nucleotides to be 2'-OH modified is a schematic that requires for the first and second nucleotides closest to the 5'end of both strands to be 2'-O-alkyl modified (see claims 201-205).

Therefore, support is not evident for a siRNA wherein the first and second nucleotides of the sense strand are 2'-O-alkyl and the rest of the nucleotides are 2'-OH, without the same schematic being present in the antisense strand. Instant claim 206 specifically requires for the antisense strand to have modifications in locations that exclude the first and second nucleotides and thus is contrary to the embodiment of the originally filed claims that requires for the rest of the nucleotides to be 2'-OH, as that embodiment also requires modification at the first two nucleotides of the antisense strand.

MPEP §2163.06 notes:

> If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981).

MPEP §2163.02 teaches that:

> Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application.

The claims are rejected for the reasons set forth above or for dependence upon one of the claims discussed above.

A review of the specification does not reveal support for where the claim amendments are found. Should applicant disagree, applicants are encouraged to point out with particularity by page and line number where such support might exist for each claim limitation added in the amended claims filed on 1/8/09.

There is no support for these claim limitations in the claimed priority documents. Therefore, the effective filing date of the instant claims is considered, for purposes of prior art, to be 10/19/06, which is the filing date of the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 201, 202, 206, 207, 213, 220, 221, 224-228, and 230-233 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giese et al. (US 2004/0180351 A1), in view of Elbashir et al. (The EMBO Journal, 2001, Vol. 20, No. 23, pages 6877-6888), and Vargeese et al. (US 2004/0110296 A1).

It is noted that the Giese et al. and Vargeese et al. references are cited and of record on the PTO-892 mailed on 9/8/08.

The instant claims are directed to a siRNA 18-30 bases in length comprising a sense strand and an antisense strand, wherein the first and second nucleotides closest to the 5' end of the sense strand have a 2'-O-alkyl modification and the remainder of the nucleotides are 2'-OH modified; and an antisense strand that is at least substantially complementary with the mRNA of the target gene and the sense strand. Furthermore, a first nucleotide of the antisense strand closest to the 5' end of the antisense strand is phosphorylated at its 5' end and the sense strand is devoid of a phosphate at its 5' end; the antisense region includes at least one nucleotide other than first and second antisense nucleotides having a 2' modification; the antisense strand has at least one phosphorothioate internucleotide linkage; a 3' overhang of 1-5 nucleotides on at least one of the sense or antisense strand; and a conjugate, more specifically a cholesterol conjugate.

Giese et al. teach siRNA molecules comprising a sense and an antisense strand, comprising a sense region and an antisense region, respectively, wherein the antisense

region is complementary with the mRNA of a target gene and is complementary with the sense region.

Giese et al. teach various combinations and patterns of modifications for siRNA duplexes. Giese et al. teach that the siRNAs can be blunt-ended or can comprise a 3'-overhang of at least one nucleotide on the sense or antisense strand. Giese et al. teach siRNA molecules fully modified with 2'-O-methyl modifications, as well as siRNA modification schematics with alternating 2'-O-methyl regions (see Figure 2, for example). Giese et al. teach an siRNA, for example, that is fully modified with 2'-O-methyl modifications with 2 nt 3'-overhangs on the sense and antisense strands (TT) (see duplex 79A79B in Figure 8, for example).

Giese et al. teach that it is particularly advantageous to inactivate the sense strand of any of the RNAi forms of any of the embodiments, preferably via end modification, and more preferably a 5' end modification. Giese et al. teach that the advantage of this strategy arises from the inactivation of the sense strand which might otherwise interfere with an unrelated single-stranded RNA in the cell (see paragraphs [0103] and [0167]). Furthermore, Giese et al. teach that the 5' end of the antisense strand preferably has a free OH and that the 5' end of the sense strand is modified to inactivate the strand (see paragraph [0103] and Table 1, embodiments 7 and 8).

Giese et al. teach that a 5'-phosphate on the antisense strand is required for siRNA function, suggesting that cells check the authenticity of siRNAs through a free 5' OH which can be phosphorylated and allow only such bona fide siRNAs to direct target RNA destruction (see paragraph [0119]).

Giese et al. teach that each of the design elements may be combined (see paragraphs [0112] and [0113], for example). Giese et al. teach that in addition to the various modifications or designs of the inventive RNAi molecules, further or additional modification of the nucleotides may include the use of a phosphorothioate backbone of the RNAi molecules which may be either complete or partial in order to inhibit endonuclease function (see paragraph [0170]).

Giese et al. teach that 2'-O-alkyl modifications stabilize RNAi molecules against degradation, but to a certain degree this is counterbalanced by the effect that 2'-alkyl modifications generally result in a reduced knockdown activity. Giese et al. teach that accordingly, the design of RNAi molecules has to balance stability against activity (see paragraph [0176]). Giese et al. teach that the most efficient molecules were modified at alternating positions of both strands.

Giese teaches incorporation of various 2'-position modifications including amino, fluoro, methoxy, alkoxy, and alkyl (see paragraph [0024]). Giese teaches siRNA molecules wherein each strand comprises a plurality of groups of modified nucleotides having a modification at the 2'-position whereby each group of modified nucleotides is flanked on one or both sides by a flanking group of nucleotides, wherein the flanking group is either unmodified or is modified with a different modification than the modified groups (see paragraph [0025]).

Giese et al. does not teach a specific schematic wherein the first two nucleotides of the sense strand are 2'-O-alkyl modified wherein the rest of the nucleotides are 2'-OH modified and does not teach conjugates.

Elbashir et al. teach siRNAs, wherein each strand is 21-23 nucleotides in length and wherein at least 19 nucleotides of the sense strand are complementary to the antisense strand. The siRNAs taught by Elbashir et al. mediated RNAi via RISC. Elbashir et al. teach chemical modification with 2'-deoxy or 2'-O-methyl modifications. Elbashir et al. teach modification of 19% of the nucleotides of a duplex 21 nucleotides in length with 2'-deoxy modifications that retained activity.

Elbashir et al. teaches that a 5'-phosphate on the target-complementary strand of a siRNA duplex is required for siRNA function (see page 6886, column 2); the siRNA molecules comprise ribonucleotides (see Fig. 1, for example); duplexes of 21 nt siRNAs with 2 nt 3'-overhangs were the most efficient triggers of sequence-specific mRNA degradation (see abstract, for example); and modification of the overhangs (see page 6881). Elbashir et al. teaches that 2'-deoxy substitutions help to reduce the cost of RNA synthesis and may enhance RNase resistance of siRNA duplexes (see page 6885, column 1).

Vargeese et al. teach conjugates including cholesterol, wherein the cholesterol conjugate is for the delivery of a siRNA molecule (see abstract and paragraph [0009], for example). Vargeese et al. teach that the conjugates are used to facilitate delivery of molecules into a biological system such as a cell. Vargeese et al. teach that the conjugates can impart therapeutic activity by transferring therapeutic compounds across cellular membranes (see paragraph [0009]).

It would have been obvious to incorporate a block of 2'-O-methyl modifications at the 5' end of the sense strand and to incorporate 2'-OH modifications throughout the

rest of the sense strand, as well as to incorporate the instant modifications into the antisense strand.

It would have been obvious to incorporate a cholesterol conjugate into the siRNA molecules of Giese et al. and it would have been obvious to couple the conjugate molecule to the 3' end of the sense or antisense strand.

One would have been motivated to incorporate a cholesterol conjugate into the siRNA molecules of Giese et al. and would have been motivated to couple the conjugate molecule to the 3' end of the sense or antisense strand because Vargeese et al. teaches that cholesterol conjugates are used to facilitate delivery of molecules into a biological system such as a cell and can impart therapeutic activity by transferring therapeutic compounds such as siRNAs across cellular membranes. Since Vargeese et al. teach the advantage of conjugating nucleic acids including siRNAs to conjugates such as cholesterol to enhance the delivery of the molecule; one would have been motivated to incorporate the conjugate into the siRNA of Giese et al. to enhance the delivery thereof. Furthermore, since Giese et al. teaches chemical modifications to enhance the stability of the siRNA molecule, one would have certainly been motivated to incorporate other means of enhancing the delivery of the molecule as well, such as cholesterol conjugation, as taught by Vargeese et al.

With regards to the cholesterol conjugate being coupled at the 3' end of the sense or antisense strand, this is considered an element of routine optimization to determine the optimal location within the duplexes of Giese et al. Moreover, Giese et al. teaches that necessity of a 5' phosphate on the antisense strand for active siRNA

molecules, therefore one would have been motivated to incorporate the conjugate at the 3' end. Additionally, Vargeese et al. teaches configurations for coupling the conjugates which is within the realm of routine optimization.

It would have been prima facie obvious to perform routine optimization to determine optimal location for coupling the cholesterol conjugate of Vargeese et al., as well as to incorporate the chemical modifications of Giese and Elbashir in various combinations/locations, especially within the guidelines of Giese with regards to inactivating the sense strand and maintaining an active antisense strand, as noted in *In re Aller*, 105 USPQ 233 at 235,

> More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.

Routine optimization is not considered inventive and no evidence has been presented that the particular administration ranges used were other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art.

One would have been motivated to incorporate a block or blocks of 2'-O-methyl modifications and to combine these modifications with stretches of unmodified nucleotides or stretches of modified nucleotides, wherein the modifications are different from 2'-O-methyl modifications in view of the teachings of Giese. It is within the realm of routine optimization to combine the siRNA modifications of the prior art into various modification schematics to optimize the activity and stability of the molecule. It appears

that the inventive feature upon which applicant is relying is modification of the 5' end of the sense strand to inactivate the sense strand combined with modifications of the antisense strand that yield an active strand. Importantly, this feature is taught by Giese et al. Although Giese et al. does not teach the instant specific configuration, Giese teaches that it is particularly advantageous to inactivate the sense strand of any of the RNAi forms of any of the embodiments, preferably via end modification, and more preferably a 5' end modification. Giese et al. teach that the advantage of this strategy arises from the inactivation of the sense strand which might otherwise interfere with an unrelated single-stranded RNA in the cell; that the 5' end of the antisense strand preferably has a free OH and that the 5' end of the sense strand is modified to inactivate the strand. Furthermore, Giese et al. teach that a 5'-phosphate on the antisense strand is required for siRNA function, suggesting that cells check the authenticity of siRNAs through a free 5' OH which can be phosphorylated and allow only such bona fide siRNAs to direct target RNA destruction.

Therefore, Giese teaches to inactivate the sense strand via modifying the terminal 5'nucleotide; teaches that the antisense strand requires a 5'-phosphate for function; teaches incorporation of combinations of the instant chemical modifications. Although Giese does not teach to specifically modify the first two nucleotides to inactivate the sense strand, it is certainly within the realm of routine optimization to extend the modification via one nucleotide, especially given that Giese teaches throughout the document that modifications are preferably incorporated in blocks of one or more nucleotides. One would have been motivated to inactivate the sense strand via

incorporating a block of modifications at the 5' end of the sense strand in view of Giese et al. Given that the resultant sense strand would be inactive, one would have been motivated to modify the rest of the sense strand with 2'-deoxy modifications given that Elbashir et al. teaches that 2'-deoxy modifications reduce the cost of RNA synthesis.

Finally, one of skill in the art would have had a reasonable expectation of success at incorporating a cholesterol conjugate into the siRNA molecules of Giese et al. and would have a reasonable expectation of success when coupling the conjugate molecule to the 3' end of the sense or antisense strand because Giese et al. teaches that a 5' phosphate on the antisense strand is necessary for activity and Vargeese et al. teaches the advantages of conjugating nucleic acids such as siRNAs to conjugates such as cholesterol. One would reasonably expect for a cholesterol conjugate to benefit the delivery of the siRNA molecules of Giese et al. given the teachings of Vargeese et al.

Furthermore, one of skill in the art would have had a reasonable expectation of success in optimizing the siRNA molecules of Giese via terminally modifying one or more nucleotides of the 5'end of the sense strand to inactivate the sense strand and incorporating chemical modifications that were known to enhance the stability and activity of siRNA molecules in combination with each other, as taught by Giese and Elbashir. One would reasonably expect that incorporation of each of the prior art design elements (modifications) in combination within the guidance of Giese et al. regarding modification in blocks/combination and strategy for inactivating the sense strand and maintaining an active antisense strand to result in an active siRNA molecule.

Thus in the absence of evidence to the contrary, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Response to arguments considered pertinent to the instant rejection

Applicant argues that Giese defines terminal modification as the terminal nucleotide, rather than incorporation of modifications at the first two nucleotides to inactivate the sense strand. However, Giese et al. teaches the concept of inactivating the sense strand via terminally modifying it and teaches various embodiments throughout the document regarding the preference of incorporating modifications in blocks of one or more modification. It is considered obvious and certainly within the realm of routine optimization to extend the terminal modification by one nucleotide, given that the objective and result of inactivating the sense strand is the same.

Although applicant points to a teaching in Giese regarding that the penultimate nucleotide is unmodified, this is a teaching with regards to one embodiment of Giese and does not set forth that the penultimate nucleotide should never be modified, which is contrary to the remainder of the teachings of Giese. The one embodiment of Giese that is pointed to by applicant is not a teaching away with regards to never extending the terminal modification past the first nucleotide.

Applicant argues that there is no valid reason provided by Giese to only modify the first two nucleotides of the 5'-end of the sense strand. It is assumed that applicant is referring to 2'-O-alkyl modifications because the instant claims require 100%

modification of the sense strand with two 2'-O-alkyl modifications in combination with 2'-deoxy modifications. A valid reason to terminally modify the sense strand is clearly set forth in Giese, wherein Giese teaches the benefits of terminally modifying the sense strand to inactivate it. Modifying one vs. two nucleotides is within the realm of routine optimization, given that the result is the same, sense strand inactivation. Modifying the remainder of the strand with 2'-deoxy modifications is a newly added limitation which necessitated this new rejection and is addressed by Elbashir et al., wherein Elbashir et al. teaches that 2'-deoxy modifications reduce the cost of RNA synthesis. Given that Giese et al. sets forth motivation to inactivate the sense strand via terminal modification, one of skill would have certainly been motivated to incorporate 2'-deoxy modifications in the rest of the strand to reduce RNA synthesis costs.

Terminal Disclaimer

The terminal disclaimer filed on 1/8/09 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of application numbers 11/825,461 and 11/619,993 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMY BOWMAN whose telephone number is (571)272-0755. The examiner can normally be reached on Monday-Thursday 6:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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